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Patient Selection Criteria for Percutaneous Transluminal Coronary Angioplasty

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Public Health Service Assessment

Patient Selection Criteria for Percutaneous Transluminal Coronary Angioplasty of a Stenotic Lesion in a Single Coronary Artery

1985

INTRODUCTION

Percutaneous transluminal coronary angioplasty (PTCA) is an angiographic technique used to improve myocardial blood flow by dilating focal atherosclerotic stenoses in coronary arteries. The technique consists of mechanically induced coronary vasodilatation and recanalization. It is expected to result in the restoration of blood flow through segmentally diseased coronary arteries (1). PTCA involves the passage of a balloon-tipped flexible catheter into a site of arterial narrowing. The balloon is inflated in situ to dilate and recanalize the obstructed vessel (2). The procedure is performed by specially trained physicians on hospitalized patients with symptomatic coronary artery disease (CAD) who meet the required patient selection criteria. The purpose of this report is to reassess the patient selection criteria previously recommended for candidates who may benefit from PTCA.

The first clinical dilatation of blood vessels was described by Dotter and Judkins in 1964 (3). They used serial catheters of increasing external diameter telescopically inserted through the atherosclerotic lesion to mechanically expand the obstructed area of the vessel. The catheter system was applied initially to short segmental obstructions of the femoro-popliteal area and later to iliac arteries (4). This approach was modified by Gruentzig in the early 1970s with the development of a double-lumen, balloon-tipped catheter that could be inflated and deflated to achieve a similar dilatation effect. After

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extensive investigation in peripheral and renal arteries, Gruentzig developed a miniaturized version of the balloon catheter for use in the coronary arteries (5). In 1977, Gruentzig and co-workers first used PTCA to dilate segmental coronary artery stenosis in a patient suffering from ischemic heart disease (4).

By 1979, the preliminary encouraging experiences with this innovative technique and the recognition of its potential effect on the treatment of patients with symptomatic obstructive CAD prompted the National Heart, Lung, and Blood Institute (NHLBI) to establish an international PTCA Registry. The purpose of the PTCA Registry was to accumulate baseline and followup data to facilitate the evaluation of the safety, efficacy, and long-term effects of PTCA. Although the PTCA Registry did not require a strict protocol for patient selection, the participants established general criteria to ensure the careful selection of patients. The original guidelines for PTCA limited the procedure to a single concentric, proximal, noncalcified, subtotal lesion in a patient up to 60 years old presenting with angina of recent onset. Normal left-ventricular function, objective evidence of myocardial ischemia, and failure of optimal medical management in a patient who otherwise was a candidate for coronary artery bypass grafting (CABG) also were required (6,7). These guidelines were intended to enhance the success of the technique while minimizing its risk to the patient (8).

In 1981, the NHLBI sponsored a workshop to reevaluate PTCA. Data presented at the workshop indicated that PTCA, when carried out by an experienced physician in selected patients with single-vessel disease, could be performed successfully with a relatively low rate of complications. The participants stated, however, that more data were needed to assess properly the long-term efficacy and the role of PTCA in patients with multivessel disease. In August 1982, the Public Health Service (PHS) concluded that the use of PTCA for treatment of stenotic lesions of a single coronary artery was safe and effective in a small, selected group of patients for whom CABG was the likely alternative. The PHS assessment indicated that this group of patients should exhibit

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intractable angina, inadequately controlled with maximal medical therapy; have objective evidence of myocardial ischemia; and have normal ventricular function (4). The lesions believed most suitable for dilatation were those that were proximal, discrete, smoothly tapered, concentric and noncalcified.

A recent analysis of the data from the PTCA Registry, which was closed in September 1982, continues to suggest that PTCA is safe and effective in patients with single-vessel CAD who satisfy the initial selection criteria (9). The patient selection criteria, which included stable angina, evidence of myocardial ischemia, age up to 60 years, and normal left-ventricular function, have been observed in most of the PTCA Registry patients. However, failure to satisfy all of the foregoing criteria occurred in sufficient patients in whom PTCA had been attempted that a meaningful comparison of subgroups was possible. Such comparisons would help to determine whether and to what extent departure from the criteria for patient selection affects the chances of success or heightens the risk of complications (10). Although most patients in whom PTCA was attempted had single-vessel CAD (75 percent), a substantial minority of patients had double-vessel CAD. Fewer patients with triple-vessel CAD, left-main CAD, or stenosed bypass grafts have been treated with PTCA. However, growing experience with PTCA for the treatment of these and other indications has been reported (11).

The restrictive guidelines of the past 6 years are no longer limiting the application of PTCA. Recent studies report the use of PTCA in many previously excluded and "higher risk" patient subgroups, including elderly persons, patients with unstable angina, and patients with poor left-ventricular function. As a result of recent technical developments in diagnostic imaging and in catheter systems, plus greater experience in the use of PTCA by cardiologists, this technology is now considered to be therapeutic in patients with widely varying forms of CAD. These forms include patients with prior CABG, selected patients experiencing acute myocardial infarction (MI), those with multivessel disease, multilesion disease, complex lesions, and total occlusions (8,12).

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Some investigators have offered PTCA as a method of coronary revascularization in such patients, obviating medical therapy or conventional CABG. Besides reassessing the patient selection criteria previously recommended for candidates who may benefit from PTCA, this report also reviews the effects of age and lesion characteristics on PTCA outcome. Multivessel disease and other complex PTCAs will be assessed in a separate report.

BACKGROUND

Ischemic heart disease is the number one cause of death in the United States, accounting for one-third to one-half of all deaths and 50 to 75 percent of all cardiac deaths (13). In 1982, CAD caused 552,786 deaths (14). An estimated 5.6 million persons have been diagnosed as having CAD manifested by chronic angina or healed MI, but clinical manifestations can be unpredictable or absent (15). In one-third to one-half of CAD patients, death is sudden and unexpected (13).

Coronary atherosclerosis is a pathologic condition of the coronary arteries characterized by the accumulation of lipid and fibrous tissue in the vessel walls (16). As the lipid/fibrous plaque enlarges, it may become calcified, may undergo necrosis or ulceration, and may develop a mural thrombus. These conditions may result in disruption of the local vascular integrity causing reductions of blood flow to the myocardium (13).

Medical and surgical therapies for patients with CAD have evolved considerably over the past 20 years. Medical management now includes the liberal use of nitrates and the administration of beta-blockers and calcium antagonists. These agents are believed to favorably influence survival in selected patients (17). Surgical treatment of patients with CAD has evolved from procedures such as thoracic sympathectomy and epicardial abrasion to the currently favored CABG. Coronary artery bypass surgery is the treatment commonly applied in patients who have poorly controlled angina and coronary

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arterial anatomy amenable to revascularization. In 1983, 191,000 bypass procedures were performed in the United States (18). Although CABG costs are only a portion of the total expenditures for cardiovascular disease, more than $2 billion was spent on 170,000 CABG operations in 1982. CABG is estimated to account for approximately 1 percent of the total health care expenditures.

Initially, only 6 to 7 percent of the coronary bypass patients were considered to be potential PTCA candidates, a situation reflected in the 12,000 coronary angioplasties performed in 1982 (18). By 1983, the estimate of patients who were found acceptable to undergo coronary artery bypass surgery, but who could be treated with PTCA, was up to 15 percent. The actual number of coronary angioplasties performed that year was 26,000 (18). The less invasive nature of PTCA has contributed to the rapid increase in its use for widely varying forms of CAD. By some estimates, 30 to 40 percent of coronary bypass patients could be treated with PTCA (19).

The objective of PTCA is to improve flow through diseased segments of coronary arteries in order to increase patency and decrease the risk of distal coronary thromboembolic events. Proponents argue that PTCA improves myocardial blood flow by opening up focal areas of atherosclerotic coronary stenosis. The equipment used in performing PTCA consists of a two-catheter system and a calibrated pressure pump (7). The smaller of the two catheters is termed the dilatation catheter. The double-lumen dilatation catheter consists of a main and a side lumen. The main lumen is used for passing a guidewire, for obtaining pressure recordings, and for injecting contrast material necessary to fluoroscopically monitor the position of the guidewire and catheter. At the tip of the catheter is a sausage-shaped balloon. When deflated, the balloon surrounds the catheter like an umbrella. During therapy, the catheter is guided to the site of the lesion and positioned so that the balloon segment lies within the area of the arterial stenosis. For purposes of imaging, gold or other radiopaque markers define the balloon's length on the dilatation catheter shaft. The balloon is filled through the side channel with a dilute

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contrast material and inflated within the stenotic segment to a pump control pressure of 5 to 15 atmospheres. Following one or more such dilatations, the vessel's lumen diameter is usually increased and maintained after the balloon catheter is removed.

To be effective, balloon catheters must be inflated within the site of the vascular stenosis. This is accomplished by guiding catheters, which are used to gain access to a vessel, and guidewires, which are used to traverse the lesion most effectively (20). To reach sharply angulated arteries, a guiding catheter is first inserted into the orifice of the affected artery. Through this guiding catheter, a dilatation catheter can be positioned in the affected artery. Conventional dilatation catheters had short guidewires fixed at the tip to help direct the catheter into the artery and avoid injury to the arterial wall (7). This design prevented changes in the length or curvature of the guidewire after the catheter had been introduced into the coronary artery (21).

The conventional dilatation catheter with fixed guidewires has been largely replaced by catheter systems that have an independently movable, flexible-tipped guidewire within the balloon dilatation catheter. The length of the protruding tip and the direction to which the tip points can be altered by manipulating the other end of the wire. Steerability of the tip is not the only advantage of the "steerable catheter." When the guidewire is advanced into the artery to be dilated, it serves as a rail, over which the dilatation catheter can be advanced as needed without risk of entering side branches or creating false lumina (20).

The current technique is to position the guidewire through the distal tip of the dilatation catheter and pass it across the stenosis. While the guidewire is held back, the dilatation catheter is moved forward over the wire through the last part of the guiding catheter into the artery and across the stenosis. The guidewire provides additional support if the stenosis exhibits resistance against the passage of the balloon. Finally, it also allows for an exchange of dilatation catheters while the stenosis remains engaged (20). The ability to shape and direct guidewires has made it possible to reach almost any

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major branch of the coronary artery tree that has a significant stenosis. Coronary artery stenoses in distal sites or in branch vessels with abrupt angulations can now routinely be reached and crossed with newer-generation removable guidewire catheter systems (22).

Although the mechanism of balloon angioplasty is complex and not fully understood, it is thought to involve compression of the atherosclerotic plaque, disruption and splitting of the plaque and the intima and media of the artery, and stretching of the arterial wall (2). Data from experimental studies of transluminal angioplasty in atherosclerotic animal models, from angioplasty performed in autopsied human hearts, and from pathologic specimens studied after successful PTCA in human coronary arteries have shown that splitting of the atheromatous plaque occurs during angioplasty (23). Kinney and associates found that plaque and arterial wall disruption made the greatest contribution (87 to 93 percent) to the overall increase in lumen cross-sectional area (24). Plaque disruption includes shearing of the plaque-artery interface, stretching and longitudinal tearing of the arterial endothelium, and alteration of the wall's histologic substructure. According to Block, inflation of the balloon within an atherosclerotic arterial segment produces a progressively expansible force as pressure mounts within the balloon (23). As the balloon continues to inflate, the intima splits at its weakest point, where the atherosclerotic plaque is thinnest. Once the plaque splits, the artery can be dilated further with circumferential stretching of the vessel as the angioplasty balloon fills to its maximum outer diameter. The lumen of the artery is progressively enlarged as the media and adventitia are stretched by the dilating balloon and as the split in the atherosclerotic plaque widens. Block found that "controlled injury" to the atheromatous area of artery did not produce embolization of atheromatous material. He concluded that intimal damage from the angioplasty balloon may in some situations actually accelerate the atheromatous process and account for the recurrence of stenotic lesions in some patients within 6 months after a successful procedure (23).

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The outcome of balloon dilation is increased lumen size resulting in increased blood flow through the previously stenotic vascular segment. Objective measurements of blood pressure gradients across the stenotic segment can be obtained before and after the procedure. Successful PTCA results in a reduction of the arterial stenosis and a decrease in the trans-stenotic pressure gradient.

A major area of investigation in patients undergoing PTCA involves the use of medications designed to reduce restenosis. Restenosis after successful dilatation has been a persistent problem associated with PTCA. At present, the precise role and importance of anticoagulation therapy before, during, and after PTCA are undetermined. Some investigators believe that the success or failure of PTCA depends not only on the nature of the lesion and the skill and experience of the cardiologist, but also on the use of appropriate adjunctive medical therapy designed to prevent complications and to maintain maximal luminal patency (25). Athanasoulis reported that most European authors with extensive angioplasty experience advocate 3 to 6 months of anticoagulant therapy after the procedure, because this regimen appears to improve long-term patency rates (26).

In the PTCA Registry, none of the medication regimens (platelet inhibitors, anticoagulants, calcium antagonists, and nitrates) was associated with decreased rates of restenosis, but the PTCA Registry was not initially designed to investigate restenosis (27). Recent clinical and experimental observations on the pathophysiology of recurrent stenoses have shown that the exposed subendothelial elements of the vessel wall promote local platelet aggregation and stimulate thrombus formation (28). As a result of these findings, most clinicians performing balloon angioplasty appear to favor the concurrent use of platelet inhibitors; many also advocate spasmolytic agents. Long-term prospective randomized clinical trials are currently under way to assess the effects of medication on the prevention of recurrent stenosis.

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The patient selection criteria for candidacy to undergo PTCA, which were proposed in the August 1982 PHS assessment of PTCA for the treatment of stenotic lesions of a single coronary artery, were restrictive (4). The data available at that time supported the use of PTCA in these patients for the treatment of stenotic lesions of a single coronary artery. In the past 2 to 3 years, as cardiologists have gained experience and as the angioplasty equipment technology has improved, the criteria for patient selection have expanded. Although the technique of PTCA is generally well established, patient selection criteria are still evolving. Recent studies, including that of the PTCA Registry, have reported on the outcome of PTCA with "higher risk" patient subgroups. This report examines these and other studies as well as other available evidence that pertain to the adequacy of the patient selection criteria previously recommended for candidates for PTCA.

RATIONALE

The rationale for PTCA is based on the demonstration that atherosclerotic lesions can be dilated by exerting pressure from within the vessel lumen. This is currently done with a balloon dilatation catheter. The goals are to split the stenotic lesion, increase the luminal diameter, increase blood flow, and relieve symptoms and pathologic changes caused by ischemia. Proponents of PTCA argue that recent advances in technology allow the safe and effective application of this procedure to an expanded cohort of patients and that the technique is a safe and effective alternative to medical therapy and CABG in selected patients.

CABG has been the conventional surgical means of restoring blood flow distal to a stenotic lesion. In this procedure, a graft, often a segment of the patient's saphenous vein or an internal mammary artery, is used to divert blood around the stenotic lesion. Proponents of PTCA cite several advantages over CABG, including the avoidance of

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general anesthesia and major surgery and the treatment of patients who are considered poor surgical risks. PTCA also is a less invasive procedure that can be repeated in the event of restenosis and it does not prejudice the outcome of subsequent surgery. Moreover, the cost of surgery and extended hospitalization are greater with CABG than with PTCA. In addition, preliminary studies indicate that patients undergoing successful angioplasty have lower procedure-related expenses than similar patients undergoing CABG, even after costs associated with vascular restenosis are considered (29). Other studies have found that although the outcome of PTCA did not affect the rate of return to work, the time to return to work was significantly reduced when PTCA was successful (30).

REVIEW OF AVAILABLE INFORMATION

The NHLBI PTCA Registry is the largest current data base on coronary angioplasty. Although several centers have reported short-term PTCA experience in the literature, the most comprehensive information is available from the PTCA Registry established by NHLBI in 1979. The major emphasis of the PTCA Registry is the clinical course of 3,079 patients who underwent 3,390 procedures at 105 clinical facilities through September 1982 (31). The substantial body of data in the PTCA Registry provides valuable information on patient characteristics, clinical success, complications, and certain specific followup events. Investigators participating in the PTCA Registry presented their findings at a workshop on the outcome of PTCA, convened by the NHLBI in June 1983. The proceedings of that workshop have been reported in the June 15, 1984, edition of the American Journal of Cardiology.

At that workshop, Detre and associates presented data on the baseline characteristics of 2,234 PTCA Registry patients, which they used to identify factors that were independent determinants of clinical success (31). Clinical success was defined as a

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reduction in the lesion by at least 20 percent and freedom from in-hospital MI, CABG, or death. A similar analysis was carried out to identify factors that were independent determinants of the ability to traverse the lesion. Based on multivariate analyses, Detre and associates reported that for crossing the arterial lesion, the small size of the lesion (less than or equal to 90 percent luminal diameter narrowing) was the most important predictor of success. The next two most significant determinants of good clinical results were a proximal location of the lesion and the experience of the physician with more than 50 procedures. Less significant factors associated with adverse results were lesions located in the circumflex artery and the presence of calcification. The age of the patient (60 years old or older) was not a statistically significant factor, but these older patients had a 5 percent lower PTCA success rate because of a greater frequency of inability to traverse the lesion. Overall, about 60 percent of the clinically unsuccessful PTCAs were caused by inability to pass the catheter through the lesion. According to the authors, the predictors of clinical success were almost identical to those of crossing the lesion. Detre and associates concluded that favorable lesion characteristics and increasing physician experience were more important determinants of clinical success than patient selection criteria such as age, sex, extent of CAD, and type of angina (31).

In their presentation, Cowley and co-workers analyzed acute coronary events reported for the 3,079 patients enrolled in the PTCA Registry (32). They reviewed the frequency, outcome, and predictors of these acute coronary events, which included coronary vascular and myocardial ischemic events. Coronary dissection, occlusion, and spasm were the most common vascular events. Myocardial ischemic events included MI and prolonged angina, which was defined as chest pain persisting longer than usual or angina unrelieved promptly with sublingual or parenteral nitroglycerin. One or more acute coronary events were reported in 418 patients (13.6 percent) during or after

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attempted PTCA. A major complication, including MI, emergency CABG, or death, occurred in 67 percent of patients with acute coronary events.

Cowley and co-workers found an increased frequency of acute coronary events in patients with unstable angina and in those with severe stenosis (32). MI and prolonged angina also occurred more often in patients without previous MI. The authors noted that eccentric lesions were associated with a higher rate of coronary events; single discrete lesions were associated with lower adverse event rates than were other types of lesions. These findings are consistent with the original guidelines, which suggested that concentric, discrete lesions are most suitable for PTCA. They are also consistent with an earlier observation by Meier and colleagues that lesion eccentricity is associated with less favorable results (33). In a related report, Cowley and associates found that emergency CABG was most often necessary in patients in whom lesions could not be reached or traversed (34). Using multivariate analysis, they identified lesion eccentricity as the only significant predictor of increased frequency of emergency CABG.

Cowley and co-workers also concluded in two reports that a definite learning curve occurs with PTCA. They found a slight decline in the incidence of emergency CABG as experience increases with the use of PTCA (34). There was also a significant decline in the incidence of myocardial ischemic events and myocardial infarction with increasing investigator experience (32).

Dorros and co-workers presented a report at the workshop that analyzed the in-hospital deaths of patients in the PTCA Registry (35). Twenty-nine of the first 3,079 patients enrolled in the PTCA Registry died during their hospitalization. Analysis of the 29 in-hospital deaths (0.9 percent) revealed that 19 (0.6 percent) were related to PTCA and 10 were not. According to Dorros and co-workers, overall mortality was adversely affected by such factors as female sex, the presence of previous CABG, the presence of left-main CAD, the duration of angina, and age older that 60 years. Unstable angina and ejection fraction were not significant risk factors for mortality. For PTCA-related

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deaths, the authors reported that only female sex is a risk factor. Those deaths judged not to be related to PTCA were associated with complications of CABG (35).

Mock and colleagues reported on the PTCA Registry experience with patients ages 65 years or older (36). Because the patient selection guidelines for PTCA recommended choosing patients under 60 years of age, only 370 of the 3,079 patients enrolled in the PTCA Registry were over 65. Compared with the younger age group, the older group had a significantly greater proportion of women (38 percent versus 21 percent, p less than 0.01) and of patients who had undergone previous CABG. In the older patient group, more patients presented with severe angina and angina at rest. A larger percentage of older patients had angiographic evidence of multivessel CAD and had ejection fractions below 30 percent (36). However, the locations of the stenoses in which dilation was attempted were comparable in the two groups.

According to Mock and colleagues, the overall clinical success rate was significantly lower in the older group (53 percent) than the younger group (62 percent). A larger percentage (30 percent) of older patients had stenoses that could not be crossed with the dilating catheter. The authors suggested that this problem may be related to more tortuosity in the vessels of the older patients, because stenoses that were passed were just as likely to be successfully dilated (36). They also found that the older patients had a significantly higher in-hospital mortality rate (2.2 percent) and a greater need for elective CABG (25 percent). However, because CABG results in higher morbidity, prolonged hospitalization, and mortality in the older patient group, PTCA may offer an alternative to CABG in the highly selected symptomatic older patient. The authors indicated that the mortality rate with PTCA in the older group was still lower that that reported after CABG, but they cautioned that there were major differences in extent of CAD and left-ventricular dysfunction between the two groups. They concluded that only a randomized clinical trial could determine the true comparability of PTCA with CABG in the older patient (36).

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To determine if the PTCA Registry guidelines for PTCA eligibility were too restrictive, Bentivoglio and co-workers investigated the effects of relative contraindications on the immediate and long-term results of PTCA (10). The authors analyzed the clinical data and immediate results of 1,939 patients in the PTCA Registry with a single stenosis of just one coronary artery. They also investigated the long-term results in 998 patients with successful PTCA and adequate followup. Although unstable angina was a relative contraindication, it was present in 1,273 patients (66 percent), whereas stable angina was present in only 666 (34 percent). According to Bentivoglio and co-workers, the PTCA Registry data indicated there was no difference in immediate results between subgroups with stable and unstable angina in single-vessel disease. Followup was achieved in 346 patients with stable angina and 641 with unstable angina. The only significant difference between the groups was in the higher rate of followup CABG in patients with unstable angina. The authors found that when repeat PTCA and CABG were considered jointly under "any revascularization," the difference was not significant (10). The authors noted a significant difference in patients who had had angina for more than 1 year, compared with patients who had had angina for a shorter duration. Immediate success rate was significantly lower in patients with a longer duration of angina. Also noted was a significantly lower success rate for patients older than 60 years. Patients with longer duration of angina were also significantly older (10).

Bentivoglio and co-workers also reviewed the relationship of other relative contraindications to PTCA outcome. Relative contraindications include previous MI, nonproximal and eccentric lesions, and impaired ejection fractions. They found that, like unstable angina, previous MI did not adversely affect the immediate or long-term results of PTCA. The authors suggested that this outcome was probably due to the selection of patients who experienced uncomplicated MIs (10). The authors reviewed angiographic data and found a lower success rate when the stenosis was not proximally located, was

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eccentric, or was calcified. In addition, the rate of major complications was higher when the obstruction was elongated, irregular, and eccentric.

A higher rate of major complications (including death) was also reported for patients with impaired left-ventricular function. Although the authors found similar success rates in patients with good (50 percent or greater) and with impaired (less than 50 percent) ejection fractions, they suggested caution when PTCA is performed in patients with impaired left-ventricular function. Because more than 95 percent of the PTCA Registry patients with a single stenosis of just one coronary artery had good left-ventricular function, it is difficult to form conclusions about the effect of ejection fraction on the outcome of PTCA in patients with single-vessel CAD. Bentivoglio and his co-workers suggested that the caution regarding ventricular function may be more relevant to patients with multivessel CAD (10).

Bentivoglio and co-workers concluded from analysis of the PTCA Registry data that in experienced hands PTCA can be performed safely and effectively in many of the patients who would have been considered relatively poor candidates by the initial conservative guidelines (10). They further suggested that the availability of improved devices, awareness of the higher risks associated with unfavorable geometry of the stenosis, and poor left-ventricular function will reduce the adverse outcomes in patients with relative contraindications to PTCA. They recommended that cardiologists cautiously relax the guidelines but only after acquiring adequate experience in performing the procedure (10).

As with all sophisticated techniques, cardiologists who perform PTCA show a learning curve that is experience determined (37). To evaluate the PTCA learning curve, Kelsey and associates examined the PTCA Registry success rates and complication rates by calendar year and investigator experience (38). They found success rates improved by calendar year, from 54 percent in 1979 to 66 percent in 1981. Meir and Gruentzig reported at the third PTCA workshop that the angiographic primary success rate at

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experienced centers has continued to improve and reached 91 percent in 1982 (37). At Rhode Island Hospital, one of the participating hospitals in the PTCA Registry, the PTCA success rate for 69 patients between 1977 and 1981 was 57 percent; in 1984, the success rate for 100 consecutive patients there was reported to be 96 percent (39).

With increasing investigator experience, Kelsey and associates found a steady increase in the clinical success rate (relief of angina) and in the angiographic success rate (the mean change in stenosis of the lesions treated) (38). The authors reported that the success rate among investigators in the PTCA Registry with fewer than 50 cases was 55 percent, whereas the success rate among investigators with at least 150 procedures was 77 percent. Improvement in the PTCA success rate was also demonstrated by Meier and Gruentzig, following analysis of the results of PTCA in the most recent 50 patients of nine different investigators (37). The primary success rate for these cardiologists ranged from 84 to 94 percent. The authors believe that during the first 100 cases physician skill is probably the most important contributor to improvements in outcome, but later, other factors, such as changes in technology and patient selection, predominate (37).

Before the availability of steerable catheters, Meier and Gruentzig reported that 18 percent of the failures of PTCA were the result of an inability to reach the stenosis (37). Since the introduction of these new catheters, the failure rate has been reduced to approximately 8 percent. According to Meier and Gruentzig, new methods of custom-shaping guiding catheters during the procedure and the development of new types of guiding catheters have virtually eliminated the occurrence of unreachable orifices and have proved helpful in crossing tight lesions by providing more backup support (37). Kelsey and associates also credit physician experience and improved equipment for the increased ability to cross lesions and the improvement in success rates (38). The majority of findings reported in this assessment, however, do not reflect the influence of these advances.

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On the basis of a review of 526 patients undergoing PTCA, Meier and co-workers recommended that PTCA of long and eccentric stenoses should be attempted only by physicians with extensive experience in the procedure (33). According to the authors, these two morphologic characteristics of the lesion, while not absolute contraindications to PTCA, are likely to render the procedure more difficult, more risky, and less successful. They concluded that long and, especially, eccentric stenoses require more alertness, skill, and time of the investigator, as well as sophisticated equipment, such as steerable catheters (33).

One of the more recent uses of PTCA has been the treatment of selected patients with single-vessel CAD and unstable angina when revascularization appears desirable. Unstable angina pectoris has gained acceptance among cardiologists and cardiovascular surgeons as a distinct syndrome within the clinical spectrum of ischemic heart disease, bridging the gap between chronic stable angina and acute MI (40). Unstable angina is considered by some to be a well-established prodromal syndrome of MI and acute cardiac death. Despite many studies on this subject, there is widespread disagreement about the definition of unstable angina, the specificity of its clinical diagnosis, the factors predicting prognosis, and the comparative efficacies of modern medical and surgical treatment for this condition (41).

Recently, three studies have reported on the role of PTCA in patients with unstable angina pectoris. Williams and co-workers evaluated 17 patients presenting with unstable angina who were treated with aggressive medical therapy followed by PTCA (42). PTCA was judged successful in 76 percent (13 of 17) of all patients, causing an improvement in angiographic luminal narrowing as well as regional coronary blood flow. The authors reported that successfully dilated patients demonstrated marked relief of angina symptoms and no objective evidence of myocardial ischemia (42). Satisfactory results with PTCA in 40 patients with unstable angina were also reported by Meyer and

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associates (43). In comparing these patients with patients who had stable angina, the authors found no differences in initial success rate or complications.

Data from the most recent and largest of the three studies were presented by Faxon and colleagues at the third NHLBI workshop on the outcome of PTCA (44). To help determine the role of PTCA in the treatment of unstable angina, they compared the risks and advantages of PTCA with those of conventional CABG in similar patients with unstable angina (44). They examined the immediate and long-term results of PTCA in 442 PTCA Registry patients with single-vessel CAD and unstable angina. Then they compared these patients with 214 similar patients in the PTCA Registry who had stable angina and with 330 patients from the NHLBI Coronary Artery Surgery Study Registry who had unstable angina and underwent CABG. Patients with unstable angina who had surgery, those with unstable angina who underwent PTCA, and those with stable angina who underwent PTCA were similar in most baseline characteristics.

According to Faxon and colleagues, similar success rates of PTCA were found for patients with unstable (61 percent) and stable (63 percent) angina (44). The complication rates of PTCA were the same and the in-hospital mortality and MI rates were low in both groups. At 18 months, the combined mortality and MI incidence was about 11 percent for the patients with unstable angina and about 9 percent for those with stable angina. The findings of Faxon and colleagues suggest that PTCA in unstable angina can be done safely, and that the initial and long-term results are similar to those achieved in patients with stable angina (44).

The findings of Faxon and colleagues also show that PTCA appears to compare favorably with CABG for therapy of selected patients with unstable angina and single-vessel CAD (44). No differences were observed in the mortality and MI rates for patients with unstable angina treated surgically or with PTCA. The authors found that both revascularization procedures markedly reduced angina. Ninety-two percent of the PTCA group reported improvement in their angina, whereas 80 percent of the surgical group

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had a reduction in angina. The authors believe that these findings support the continued use of PTCA in the treatment of unstable angina. Moreover, despite the limitations of this type of observational study, they believe the results from these comparisons suggest that PTCA could be considered as an alternate form of therapy in patients with unstable angina and single-vessel CAD who require revascularization (44).

In a related study, David and co-workers evaluated the use of PTCA as a treatment in patients with variant angina (45). Among the first 83 patients treated by the investigators, variant angina was recognized in 11 cases. In all but 1 of these cases the investigators achieved technically successful PTCA, but variant angina recurred after successful PTCA in 9 patients. Among the 9 patients with variant angina after successful PTCA, 7 developed restenosis, 5 at the site of PTCA; 2 others developed severe lesions adjacent to the site of PTCA within 4 months after the procedure (45). The study shows that PTCA is technically feasible in patients with variant angina and coexisting coronary stenosis, but the results indicate the PTCA alone is inadequate treatment for variant angina. According to David and co-workers, the results of their experience with PTCA in patients with angina decubitus who do not have variant angina have been excellent. They concluded that patients with variant angina may not benefit from PTCA and should be treated with calcium antagonists whether PTCA is performed or not (45).

Variant angina is believed by some to be caused by coronary artery spasm. Evidence is mounting to suggest that coronary spasm plays a significant role in the pathogenesis of chest pain in all the unstable angina pectoris syndromes (46). It has been demonstrated that decreased coronary artery blood flow may result from coronary artery spasm while myocardial oxygen demand remains stable. Coronary artery spasm can be recognized angiographically by transient variation in segmental luminal diameter; in most instances, it occurs in the presence of coronary stenoses.

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Recently, Bentivoglio and co-workers conducted a prospective study to determine the influence of coronary spasm on the immediate results and complications of PTCA. They sought to evaluate the possible long-term effects of coronary spasm when associated with fixed stenosis in patients successfully treated with PTCA (46). Eight patients with unprovoked spasm were the subject of their report. Six of the eight patients had successful PTCA; the six patients treated successfully by PTCA all received nitrates and nifedipine. On followup, three of the six were asymptomatic while the other three experienced chest discomfort similar to their attacks before PTCA. On the basis of these eight cases, Bentivoglio and co-workers suggested that, in patients with coronary artery stenosis, associated spasm does not reduce the chances of successful PTCA. They cautioned, however, that because the spasm may recur, the patient should receive long-term vasodilator therapy. The authors noted that a high incidence of coronary spasm, which is associated with unstable angina, would not be uncommon in single-vessel candidates for PTCA. Therefore they recommend that patients considered to be candidates for PTCA should have intracoronary nitroglycerin administered before PTCA (46).

DISCUSSION

Percutaneous transluminal coronary angioplasty (PTCA) has evolved into an effective palliative therapy for the treatment of symptomatic atherosclerotic coronary artery disease in selected patients (47). Since its introduction to the medical community in 1977, PTCA has become increasingly accepted as an alternative therapy to CABG for single-vessel disease (8). Initial clinical trials using PTCA for selected patients with CAD appear to have been successful and to indicate significant potential for altering the types of patients chosen for revascularization surgery (48). Data from the NHLBI PTCA Registry indicate that PTCA can reduce the extent of coronary artery stenosis. In

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addition, successful PTCA can relieve angina pectoris and improve objective signs of myocardial ischemia (49). Whether these benefits can be obtained with a combined mortality and morbidity rate less than or similar to the rate associated with CABG or medical therapy has not been conclusively answered. PTCA has been shown to be effective in relieving angina and improving functional capacity, but only a randomized clinical trial can provide reliable data on the true efficacy of PTCA and its comparability with CABG and medical therapy in patients with symptomatic ischemic heart disease.

Until recently, the major indication for PTCA has included the presence of intractable angina inadequately controlled with maximal medical therapy. However, as a result of the findings previously cited, the safety and efficacy of PTCA are sufficiently established to support an expansion of that indication to include patients whose angina is not "intractable despite maximal medical therapy." Candidates for PTCA, with angina pectoris refractory to optimal medical management, would include patients who cannot tolerate medication, are noncompliant, or feel that the psychological burden placed upon them by their CAD is such that they cannot continue medical therapy despite angina that is controlled (19). There is no current evidence that revascularization therapy, either CABG or PTCA, will prolong life in single-vessel disease when the patient has stable angina (50,51). Revascularization is undertaken principally for the relief of symptoms and functional improvement. According to Hollman, patients differ on what constitutes acceptable relief of symptoms. A patient's degree of dissatisfaction with his or her cardiac disability is therefore as important as the patient's formal functional class (50). Accordingly, PTCA would be indicated for patients who have symptomatic single-vessel disease that interferes with their usual lifestyle or for patients whose activities would have to be significantly restricted as part of the medical therapy. Candidates for PTCA should be operable.

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Patients must be aware that the restenosis rate is between 25 and 35 percent and that serious complications, such as emergency CABG, MI, or death may occur. Cowley and co-workers reported that 6.6 percent of the 3,079 patients in the PTCA Registry required emergency CABG (34). In the PTCA Registry, emergency operations were associated with a 6.4 percent mortality. An additional 41 percent of the patients who required emergency operations had a nonfatal perioperative MI. Data from recent studies reporting early PTCA experience are consistent with the PTCA Registry data (52). Acinapura and colleagues reported that emergency CABG was required in almost 11 percent of the 198 patients who underwent PTCA. There were no operative deaths, but perioperative MI occurred in 38 percent of the patients who required emergency CABG. Recurrent symptoms developed in 31 (21.8 percent) of the 142 patients who had undergone initially successful angioplasty (52).

Some investigators believe there are circumstances when revascularization should be considered in the absence of symptoms, even though there is no evidence to date that PTCA is of benefit in asymptomatic patients (19). These investigators consider the amount of myocardium at risk an important variable and recommend PTCA in asymptomatic patients if large amounts of myocardium are at risk and objective evidence of myocardial ischemia can be demonstrated by stress testing (19,50). Gruentzig reported that some patients with stenoses involving proximal segments of major arteries, jeopardizing large areas of myocardium, may present with no symptoms or mild ones. He found that patients with severe proximal lesions in the left-anterior descending artery are associated with poor prognoses, even in the absence of significant symptoms. He recommended that these patients in particular should be considered for PTCA independent of their symptomatic status (19). Patients with borderline or insignificant lesions in whom no objective evidence for myocardial ischemia can be demonstrated, however, should not be treated with PTCA (50). Hollman reports that such patients are more likely to have serious myocardial loss if PTCA is complicated by

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dissection or acute occlusion (50). He found that such patients may develop a recurrent stenosis at the site of angioplasty that is more severe than the original lesion. If large areas of myocardium are jeopardized and objective evidence of myocardial ischemia is evident, PTCA should be considered even if the symptoms are mild or absent.

A major area of dispute has been the role of revascularization (CABG or PTCA) as an alternative form of therapy for selected patients with single-vessel CAD and the syndrome of unstable angina. Although patients with unstable angina are usually considered to be a more or less homogeneous group, they consist of a number of distinguishable subgroups, which may explain the widely differing estimates of prognosis in patients considered to have unstable angina (13). The amount of CAD varies considerably in patients with unstable angina. Most patients have multivessel disease, while about 10 percent have only single-vessel involvement. In 1980, investigators reported the results of a large, prospective, randomized, national cooperative study that compared intensive medical therapy with CABG for the acute management of patients with unstable angina. They found that most patients with unstable angina can be stabilized and managed with good medical therapy without an increased risk of early MI or death. Three months later, they recommend that the patients with severe CAD or persistent angina despite medical therapy consider elective CABG (13).

At a recent symposium sponsored by the American College of Cardiology, Cobanoglu reported that CABG, when performed without delay, could be done safely--and with enhanced survival--for high-risk patients with unstable angina (53). He found that left-ventricular function, MI rates, and survival in this group of 1,163 patients were at least as good among patients with stable or progressive angina, if not better. According to Cobanoglu, 89 percent of the unstable angina group survived, compared with 79 percent in the stable and 80 percent in the progressive angina groups, during a 9-year followup period (53).

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For PTCA to be considered an alternate form of therapy, it should effectively relieve unstable angina with a mortality and morbidity rate equal to that of CABG. The data provided by Faxon and co-workers show that PTCA compares favorably with CABG with respect to in-hospital, as well as to the 18-month, mortality and MI rates (44). In regard to the relief of angina, PTCA was also highly successful, resulting in symptomatic improvement in 92 percent of the patients. According to Faxon and co-workers and Bentivoglio and associates, there was no difference in immediate results between subgroups with stable and unstable angina in single-vessel disease. These results suggest that PTCA could be considered an alternative form of therapy in patients with unstable angina and single-vessel CAD who require revascularization.

The total experience using PTCA in cases of angina with underlying coronary artery spasm is limited. Coronary artery spasm, suggested in the past as a possible cause of variant angina, has in recent years been found to contribute, to a greater extent than previously believed, to a variety of manifestations of ischemic cardiac disease (13). Variant angina, described by Prinzmetal in 1959, was attributed to spasm of the large coronary arteries, because coronary arteriograms were frequently negative and because there was elevation and not depression of the ST segment in the ECG during pain (13). David and co-workers reported that PTCA alone is inadequate treatment for variant angina (45). Patients with variant angina or patients with unstable angina who have ischemic chest pain with ST-segment elevation should be managed medically with nitrates and calcium channel blockers. If medical management fails and revascularization is necessary, CABG appears to be the procedure of choice (54).

The original PHS recommendation regarding objective evidence of myocardial ischemia in patients who are considered candidates for PTCA is still considered a valid criterion. Most cardiologists require patients who are candidates for PTCA to demonstrate objective evidence of myocardial ischemia (19). A tentative diagnosis of ischemic heart disease may be made by means of the history, but in the absence of a

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documented infarction, a definitive diagnosis requires laboratory confirmation. Laboratory evaluation of all patients with suspected or documented CAD usually includes an ECG and chest roentgenogram. When a diagnosis cannot be established with these techniques, the indicated procedure is treadmill ECG and radioisotope studies, which in certain instances are followed by coronary arteriography.

The ECG may establish the diagnosis of ischemic heart disease if characteristic changes are present. The absence of abnormalities, however, by no means excludes the diagnosis (55). Patients who are thought to have angina pectoris but whose chest pain is difficult to interpret should have exercise stress ECGs to document the presence of myocardial ischemia (13). If patients with atypical chest pain thought possibly to be anginal have negative or equivocal exercise stress studies or if interpretation of stress ECG is unreliable, radioisotope evaluation is usually recommended. Results of exercise ECG testing and radioisotope studies will usually determine the need for coronary arteriography. In some institutions, coronary arteriography is done on almost all patients with definite or suspected angina (13). Coronary angiography is the only method that will provide unequivocal diagnostic information concerning the presence or absence of coronary atherosclerosis (55). It also permits estimation of the severity of obstructive lesions that may be present. Coronary angiography is indicated in all patients with CAD in whom surgical treatment is contemplated (13). Patients who have severe angina and who have already demonstrated arteriographic evidence of CAD certainly do not require treadmill ECG or radioisotope studies to be considered candidates for PTCA.

Ejection fraction, the ratio of stroke volume to end-diastolic volume, has become the most widely accepted of all measurements assessing left-ventricular function (13). It is an expression of the percentage of blood in the ventricle that is ejected per beat. The normal values obtained from measurements of ejection fractions range from about 56 to 78 percent. When the ejection fraction is reduced, the presence of depressed left-ventricular contractile function is suggested (55). Normal ventricular function was

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previously recommended by the PHS for candidates of PTCA and included as a requirement in the patient selection criteria of the PTCA Registry.

Investigators argue that "normal" ventricular function need not be a prerequisite for single-vessel angioplasty because the state of ventricular function has no significant bearing on the ability of the procedure to restore adequate coronary blood flow (19). Although normal left-ventricular function identifies a group of patients at lowest risk for revascularization with surgery or PTCA, the degree of left-ventricular dysfunction does not influence the likelihood of success with PTCA. Bentivoglio and co-workers found similar success rates in patients with good (50 percent or greater) and with impaired (less than 50 percent) ejection fractions (10). Ventricular function might affect the safety of the procedure should the patient have an ischemic complication (e.g., acute occlusion of the vessel being dilated). Bentivoglio and co-workers reported a higher rate of major complications, including death for patients with an impaired left-ventricular function (10).

Because many patients without normal left-ventricular function are otherwise ideal candidates for PTCA, it may not be appropriate to specify a specific ejection fraction as a patient selection criterion for patients considered to be candidates for PTCA. Within certain limits, determined by the physician, deviation from strictly normal left-ventricular function could be tolerated. Patients with diminished left-ventricular function could be considered candidates for PTCA as long as the morbidity and mortality risks of angioplasty are comparable with those of conventional surgical revascularization.

The effect of low ejection fractions on patient survival is important to the physician. An analysis of the coronary artery surgery study by Passamani and colleagues showed that CABG-treated patients with chronic stable CAD who entered the study with significantly impaired left-ventricular function fared better at 7 years than the medically treated patients (56). Survival was similar, however, for patients with single-

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and double-vessel disease and ejection fractions above 34 percent but below 50 percent in the two treatment groups. Survival of the patients with triple-vessel disease and impaired ventricular function assigned to the surgical treatment group was 88 percent in contrast to 65 percent for those assigned to the medical treatment group. The authors concluded that patients with triple-vessel disease and ejection fractions above 34 percent but below 50 percent appear to have improved 7-year survival with elective CABG. There are no similar studies reported in the literature for PTCA-treated patients.

With increased investigator experience and improved PTCA techniques, overall results will improve considerably (37,38). Recent studies from Hall and Gruentzig (57,58) now indicate an initial success rate of 87 percent for patients who undergo PTCA at Emory University Hospital, compared with the current overall immediate success rate, considered to be about 70 percent (59). According to Hartzler, the major determinants of PTCA success are the skills (experience) and equipment of the physician (8). This observation is supported by the PTCA Registry data (31,37). Sophisticated equipment, such as steerable catheters and low-profile balloon dilatation catheters, as well as extensive physician experience will enhance the successful dilatation of long, eccentric, nonproximal stenoses (33).

One patient population that could benefit considerably from these advances in experience and equipment is the elderly (persons 65 years or older). Examination of the PTCA Registry by Mock and colleagues revealed that about 30 percent of the 370 older patients who underwent PTCA had stenoses that could not be traversed by the catheter (36). It has been suggested that this problem may be related to greater tortuosity in the vessels of the elderly. Detre and co-workers reported that the increased ability to traverse a lesion which accompanies increased physician experience has markedly improved the dilatation success rate (31). According to Meier and Gruentzig, the use of new types of guiding catheters and balloons virtually eliminates unreachable orifices and helps cross tight lesions (stenosis size equal to or greater than 90 percent) (37). Tight

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lesions were identified by Detre and co-workers as the most important predictor of unsuccessful dilatation (31).

Advice and comments concerning the appropriate patient selection criteria has been sought from groups and organizations, within and outside of the federal government. An announcement of this assessment appeared in the Federal Register notice of November 5, 1984 (60). The National Institutes of Health (NIH) believes that any changes in the patient selection criteria previously recommended for candidates of PTCA should be based on well-designed clinical studies or clinical trials. These studies would show the magnitude of benefit, if any, of PTCA over the more conventional medical and surgical therapeutic alternatives. With respect to single-vessel disease, NIH believes that a candidate for PTCA should have intractable angina inadequately controlled with optimal medical therapy and should present objective evidence of myocardial ischemia. In addition to including patients with normal ventricular function, NIH would include patients with mild impairment of ventricular function in the anatomic distribution of the diseased vessel, but these candidates would have normal myocardial function elsewhere.

Since 1980, two manufacturers have received premarket approval for several models of coronary balloon dilatation catheters from the Food and Drug Administration (FDA). On the basis of safety and effectiveness data from clinical studies, these models are currently approved in patients who have CAD and are acceptable candidates for CABG. According to the FDA, these patients should have single-vessel CAD with lesions that are concentric, discrete, subtotal, noncalcific, and accessible to dilatation with a catheter. The labeling for the balloon catheters indicates that the procedure is contraindicated in patients with diffuse or calcified stenoses, left-main CAD, coronary artery spasm, or totally obstructed coronary arteries, and in patients not acceptable for CABG. The FDA has recommended that balloon catheters be used only by physicians who are experienced in coronary angiography and who have had previous experience with PTCA. The data that led to obtaining premarket approval have been published and are

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available in summary form (61,62).

It is the opinion of the American College of Cardiology that PTCA is an established procedure in the treatment of CAD in a select group of patients. The College recommends that PTCA be performed on a discrete, accessible, segmental, high-grade, significant obstruction of the coronary artery in patients who present with angina that is inadequately controlled with optimal medical therapy and who are candidates for surgical revascularization. The College stresses that this procedure should be performed only when surgical backup is available and when individuals approved by their institution perform the procedure.

The Commission on Public Health and Scientific Affairs of the American Academy of Family Physicians concluded that the use of PTCA for single-vessel disease is an acceptable method of treating CAD. The Commission stated that patients find single-vessel PTCA highly acceptable; in fact, it is preferable to and less costly than surgery.

Through its Clinical Efficacy Assessment Project, the American College of Physicians published a policy statement on PTCA in September 1983 (2), which was reaffirmed in December 1984 (personal communication). The College concluded that PTCA was a reasonable alternative to CABG surgery in patients who had high-grade stenosis confined to a single coronary artery and severe anginal symptoms despite an adequate trial of medical therapy. According to the College, despite the lower success rates of PTCA in cases of eccentric lesions, lesions with greater than 90 percent obstruction, and lesions not located in the left-anterior descending coronary artery, PTCA should also be considered a reasonable alternative in certain patients because of its reduced morbidity and cost. The College also recommends that PTCA <u>not</u> be performed in patients with less severe symptoms and mild stenosis because of the excellent prognosis of such patients when treated medically. They believe that the safety and efficacy of PTCA is directly related to the skill and experience of the personnel performing the procedure, and suggest that PTCA be performed only by

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physicians experienced with the procedure and only on candidates for CABG surgery when a surgical team is available on standby.

The Council on Scientific Affairs of the American Medical Association concluded that indications for PTCA are angina and objective evidence of myocardial ischemia, plus a lesion technically amenable to the procedure. The Council also recommends that relatively asymptomatic patients who have strong objective evidence of myocardial ischemia, or symptomatic patients whose conditions are controlled with medical treatment but who have limitations of physical activities beyond their desires, be considered for PTCA. The Council expressed the opinion that any candidate for PTCA also must be a candidate for CABG, except in the case of patients whose coexisting conditions make CABG unusually hazardous. According to the Council, PTCA should be selectively applied in patients with left-main coronary artery stenosis, a calcified plaque, and a long stenotic segment. PTCA is contraindicated with lesions that occur at the bifurcation of major vessels. The use of heparin sodium and nitrates during PTCA and the subsequent administration of an antiplatelet agent also were recommended, although there is no evidence that these measures favorably affect outcome (63).

SUMMARY

PTCA is an angiographic technique used to improve myocardial blood flow by recanalization of focal areas of atherosclerotic coronary artery stenosis. The technique involves passage of a balloon-tipped catheter into the site of arterial narrowing and inflation of the balloon to mechanically reduce the obstruction.

The NHLBI PTCA Registry provided a substantial body of data on safety and efficacy, including patient characteristics, complications, and acute coronary events. On the basis of evidence in the PTCA Registry and an increasing number of reports, the safety and efficacy of PTCA are sufficiently established to conclude that PTCA is a

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reasonable alternative to CABG in selected patients with single-vessel CAD in whom revascularization is suggested by clinical indications and in whom coronary anatomy is technically suitable for dilatation. This group of patients should exhibit angina refractory to optimal medical management, have objective evidence of myocardial ischemia, and have lesions amenable to angioplasty. Candidates for PTCA should be operable. The procedure should be performed only when a skilled surgical backup team is immediately available to perform CABG on unstable patients with acute myocardial ischemia.

The PTCA Registry data show that serious complications, defined as the need for emergency CABG, MI, or death occur in almost 10 percent of the patients who undergo PTCA. The overall complication rate is about 21 percent and the mortality rate about 0.9 percent. The recent experience of several large centers is somewhat more favorable. The PTCA Registry indicates that successes rise and complications fall as centers gain experience with the procedure.

Restenosis occurs within 1 year in 25 to 35 percent of patients who undergo angioplasty. The cause of restenosis is uncertain. Should restenosis occur, repeat PTCA has a high success and a low complication rate. If repeat PTCA is unacceptable, serious consideration must be given before PTCA is attempted.

The data from the PTCA Registry are not useful in evaluating the relative merits of PTCA and CABG for patients with CAD. A randomized clinical trial is the most effective method of providing definitive answers on the relative efficacy of the two therapies. In the absence of trials identifying the differences in outcome between PTCA and CABG, or between PTCA and medical therapy, physicians must base their therapeutic decisions on current reported results and sound clinical judgment.

Many medical specialty organizations have recommended that PTCA be performed in patients who present with angina that is inadequately controlled with medical therapy and who are candidates for surgical revascularization. Clinical groups emphasize that

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PTCA should be performed only by physicians experienced with the procedure, and only when surgical backup is available.

The FDA has given premarket approval for several models of coronary balloon dilatation catheters. The labeling for the balloon catheters indicates that the procedure is contraindicated in patients who have diffuse or calcified stenoses, left-main CAD, coronary artery spasm, or totally obstructed coronary arteries, and in patients who are not acceptable for CAGB.

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16. Abstract (Limit: 200 words)

Percutaneous transluminal coronary angioplasty (PTCA) is a technique used to improve myocardial blood flow by dilating focal atherosclerotic stenoses in coronary arteries. A balloon-tipped flexible catheter is inflated in situ to dilate and recanalize the obstructed vessel. The procedure is performed by specially trained physicians on hospitalized patients with symptomatic coronary artery disease who meet required patient selection criteria. Advantages include the avoidance of general anesthesia and major surgery. With advances in technology, coronary stenoses in distal sites or in branch vessels with abrupt angulations can now routinely be reached and crossed. PTCA does not prejudice the outcome of subsequent surgery. Data from the PTCA Registry of the NHLBI indicate that PTCA can reduce the extent of coronary artery stenosis, relieve angina pectoris and improve objective signs of myocardial ischemia in elderly patients, patients with unstable angina, and those with poor left ventricular function. Emergency CABG, MI, or death occur in almost 10 percent of the PTCA patients. The overall complication rate approximates 21 percent and the mortality rate about 0.9 percent. Restenosis occurs within 1 year in 25 to 35 percent of patients. Repeat PTCA has a high success and a low complication rate.

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NCHSR publication of research findings does not necessarily represent approval or official endorsement by the National Center for Health SErvices Research and Health Care Technology Assessment or the U.S. Department of Health and Human Services.

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